

**PROBE DEVICES PARTICULARLY USEFUL FOR
NON-INVASIVE DETECTION OF MEDICAL CONDITIONS**

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to probe devices which apply static pressure to a body part of a patient, preferably a digit (i.e., a finger or toe) of the patient, while non-invasively detecting certain medical conditions. The invention is particularly useful in the methods and apparatus described in our PCT Application PCT/IL97/00249, published as International Publication No. WO98/04182 on February 5, 1998, and in our PCT Application PCT/IL99/00292, published as International Publication No. WO 99/63884 on 16 December 1999 which publications are hereby incorporated by reference; and the invention is therefore described below with respect to such methods and apparatus.

Publication WO98/04182 discloses methods and apparatus for the non-invasive detection of a change in a physiological condition of a patient by monitoring changes in the peripheral arterial tone as manifested by changes in the arterial blood volume in a terminal extremity of a body part, preferably a digit (finger or toe) of the patient. The method and apparatus are described therein particularly for detecting myocardial ischemia and sleep apnea, and also for continuously monitoring blood pressure. The preferred constructions described therein generally include a probe for application to the patient's body part (e.g., finger). The probe includes a housing for receiving the distal end of the patient's body part, and pressurizing means for applying a static pressure field substantially uniformly around the distal end of the patient's body part, including its terminal-most extremity when received in the housing. The static pressure field is of a predetermined magnitude sufficient to substantially prevent distention of the venous vasculature, uncontrolled venous backflow, and retrograde shockwave propagation into the distal end of the body part, and to partially unload the wall tension of, but not to occlude, the arteries in the distal end of the body part when at heart level or below. The probe further includes a sensor for sensing changes in

the distal end of the patient's body part related to changes in volume therein which are due to changes in instantaneous blood volume related to arterial tone.

Publication WO98/04182 also discloses various types of devices or probes which may be used, and many applications of such devices. Some of the devices measure changes in volume in the distal end of the digit accompanying blood pressure waves, while other devices measure changes in optical density in the distal end of the digit accompanying blood pressure waves.

Further information concerning the construction and operation of such devices, as well as many of the applications in which such devices may be used, appears in our Publication WO98/04182, which is hereby incorporated herein by reference.

It was found that at times the sensors used in such devices were extremely sensitive to movements of the finger, such as finger jitter during exercises. Such movements of the finger tend to produce volume changes which could affect the accuracy of the sensor in detecting the change in the actual physiological condition of the patient being monitored.

OBJECTS AND BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide a device for application to a body part of a patient to detect a change in the physiological condition of the patient, which device exhibits less sensitivity to movements of the body part during its use. Another object of the invention is to provide a device of the foregoing type which is of a relatively simple construction, and which therefore can be produced in volume and at relatively low cost.

According to the present invention, there is provided a device for application to a body part of a patient to detect a change in the physiological condition of the patient, comprising: a housing for receiving the body part; pressurizing means for applying a pressure field around the body part; pressurizing means for applying a pressure field around the body part when received in the housing; and a sensor for sensing changes in the body part related to changes in blood volume therein; characterized in that: the housing includes at

least three contiguous but separate sections including a distal end section at its distal tip, a proximal end section at its opposite end, and at least one middle section between the end sections; the pressurizing means applies a pressure field to the portions of the body part received within at least the distal end section and the middle section of the housing; and the sensor senses changes in the body part received within the middle section of the housing.

In most of the preferred embodiments of the invention described below, the pressurizing means also applies a pressure field to the proximal end section.

According to further features described in these preferred embodiments, the housing is configured to receive a digit of the patient and includes: a closed distal end, enclosing one or more chambers, for receiving the distal end of the patient's digit; and an open proximal end, enclosing one or more additional chambers, at the opposite end of the housing and connected thereto by the middle section.

As will be described more particularly below, a device constructed in accordance with the foregoing features is less sensitive to certain movements of the patient's body part, (e.g., a finger) during the test period. This is because the sensor measurements are taken in the area of the middle chamber which is open at both ends; therefore, longitudinal movements of the finger (e.g., finger jitter during exercise) tend to produce substantially equal movements at the two ends of the middle section, such that the effects of such movements on the sensor measurements taken in the middle chamber tend to cancel each other.

In one described preferred embodiment, the housing is constituted of a plurality of parts secured together, and the chambers are also constituted of separate membranes, one secured within each of the parts. In a second described embodiment, the housing is constituted of a single part of tubular shape, and the chambers are also constituted of a single membrane of tubular shape, the device including a plurality of internal annular rings for pressing spaced annular portions of the membrane to the inner surface of the housing to define the separate fluid chambers within the housing.

A further embodiment is also described wherein the closed distal end of the housing, and the end fluid chamber therein, are of substantially shorter length than the other portions of the housing and the fluid chambers therein. In addition, the end fluid chamber in the closed distal end section of the housing includes an abutment element having a concave surface for receiving the distal tip of the patient's digit.

A still further embodiment is also described, wherein the housing is in the shape of a cylinder open at both ends, and the distal end is closed by a fluid chamber mounted therein. In one variation of this embodiment, only the fluid chamber closes the distal end of the cylinder; whereas in another variation the end fluid chamber closing the open end of the cylinder includes a rigid element mounted within the distal end of the cylinder and enclosed by the membrane defining the end fluid chamber. In the construction wherein the rigid element is enclosed by the membrane, the rigid element is formed with holes therethrough permitting the free flow of fluid within the end chamber with respect to both sides of the rigid element.

Still further embodiments are described wherein the proximal end section includes a sponge cushion rather than a pressurized chamber.

All of the foregoing embodiments may be implemented in relatively simple structures capable of being produced in volume and at a low cost.

Further features and advantages of the invention will be apparent from the description below.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 is illustrates one form of probe constructed in accordance with the present invention for application to a finger of a patient;

Fig. 2 is an exploded view of the probe in Fig. 1;

Fig. 3 is an assembled view of the probe of Figs. 1 and 2 rotated 90°;

Fig. 4 illustrates another probe constructed in accordance with the present invention;

Fig. 5 is an enlarged fragmentary view illustrating a preferred modification in the construction of the probe of Fig. 4;

Fig. 6 illustrates another probe constructed in accordance with the present invention;

Fig. 7 illustrates the probe of Fig. 6 as applied to a finger of a patient;

Figs. 8 and 9 illustrates two other probes constructed in accordance with the present invention;

Fig. 10 illustrates the probe of Fig. 9 as applied to a patient's finger;

Fig. 11 illustrates a modification in the probe of Fig. 1;

Figs. 12 and 13 illustrate two further probe constructions, including a sponge cushion in the proximal end section rather than a pressurized chamber; and

Fig. 14 illustrates a still further probe construction including two optical sensors.

DESCRIPTION OF PREFERRED EMBODIMENTS

The Device of Figs. 1-3

The device illustrated in Figs. 1-3 is generally similar to those described in the above-mentioned Publication WO98/04182, in that it includes: a housing 10, for receiving a body part of a patient, in this case a digit (preferably a finger) of the patient, to detect certain changes in the physiological condition of the patient; pressurizing means for applying a pressure field, preferably a static, uniform pressure field, around the patient's digit when received in the housing 10; and a sensor for sensing changes in the patient's digit related to changes in blood volume therein. The pressurizing means includes a deformable membrane of elastomeric material defining one or more fluid chambers with the housing, and a pressure source for applying a static fluid pressure to the chambers.

Publication WO98/04182 discloses a number of constructions in which the housing is constituted of a single section having a single fluid chamber, or two sections each having a fluid chamber. In the two-section construction, the sensor measurements are taken from the chamber of the distal section (with respect to the patient's heart), and senses changes in the distal tip of the patient's digit received in that section.

An important difference in the device illustrated in Figs. 1-3 of the present application, over those described in Publication WO98/04182, is that the housing in the device of Figs. 1-3 includes at least three contiguous but separate sections, namely a distal end section at its distal tip, a proximal end section at its opposite end, and at least one middle section between the end sections. These housing sections thus define at least three separate fluid chambers, namely one chamber within each end of the housing, and at least one chamber within the middle portion of the housing. The sensor senses changes in the portion of the patient's digit received within the middle chamber defined by the middle section of the housing. Since this middle chamber has an end chamber on each side and is therefore open on each side, longitudinal motions of the body part occurring during the time the test is performed (e.g., finger jitter during an exercise) tend to cancel each other, as will be described more particularly below, thereby making the device less sensitive to movements of the body part during the measurement period.

The structure of the finger probe 10 illustrated in Figs. 1-3 is best seen in the exploded view of Fig. 2. It includes a rigid housing constituted of three contiguous sections, namely: a thimble-shaped cap 11 defining the distal end section at the closed distal end of the housing; an annular collar 12 defining the proximal end section at the open proximal end of the housing; and an intermediate sleeve 13 defining the middle section secured between the thimble-shaped cap 11 and the annular collar 12. A first annular ring 14 secures one end of the intermediate sleeve 13 to the open end of the thimble-shaped cap 11; and a second annular ring 15 secures the opposite end of the intermediate sleeve 13 to one end of the annular collar 12. A third annular ring 16 is provided

at the opposite end of the annular collar 12, constituting the proximal end of the probe housing 10 through which the patient's finger is introduced.

The three housing sections defined by parts 11, 12 and 13 enclose three separate chambers defined by three separate membranes, namely: a distal membrane 21 within the thimble-shaped cap 11 at the distal end of the housing; an annular membrane 22 within the annular collar 12 at the proximal end of the housing; and an intermediate annular membrane 23 within the intermediate sleeve 13 at the middle section of the housing.

The distal membrane 21 is also of a thimble-shape as housing part 11, and has an open end which is secured within the housing cap 11 by annular ring 14. Annular membrane 23 within the intermediate sleeve 13 is secured at its end facing cap 11 also by ring 14, whereas its opposite end is secured by ring 15. Annular membrane 22 within the annular collar 12 is also secured at its end facing intermediate sleeve 13 by ring 15, and its opposite end by ring 16.

The probe illustrated in Figs. 1-3 is of the type which includes a substantially U-shape restraining bar, shown at 24 in Figs. 2 and 3. As described with respect to the embodiment of Figs. 7a and 7b in Publication WO98/04182, incorporated herein by reference, the U-shaped restraining bar 24 is mounted by its legs 25, 26 to annular ring 14 to be disposed within the distal membrane 21 and to press it against the inner surface of the thimble-shaped cap 11. Bar 24 thus divides the chamber defined by that end cap into two sub-chambers to be located on opposite sides of the distal tip of the patient's digit when inserted into the probe housing. The provision of this restraining bar produces a two-point clamping action on the inserted finger and resists pop-off, as well as axial and rotational movements, of the finger relative to the probe housing. Preferably, the U-shaped bar 24 is shaped so as to permit fluid communication between the two sub-chambers within that part of the probe housing. If such fluid communication is not provided for, each sub-chamber would require its own pressurizing means.

The three parts 11, 12, 13 of the probe housing 10, are each formed with an opening 31, 32, 33, respectively, providing communication with their respective fluid chambers. Openings 31 and 32 in housing parts 11 and 12 are

connected by a common tube 34 to a pressure source 35 for applying a static pressure field to the fluid chambers in these two parts, constituting the distal and proximal ends, respectively, of the probe housing. Opening 33 in the intermediate sleeve 13 is connected by a separate tube 36 to the same pressure source 35, but in addition, to a volume change sensor 37, which measures change in volume within the middle section of the probe housing 10 defined by the intermediate sleeve 13.

The apparatus illustrated in Figs. 1-3 is otherwise constructed and operates in substantially the same manner as described in Publication WO98/04182. However, since sensor 37 is associated with the fluid chamber within the intermediate sleeve 13, and since sleeve 13 is open at its two opposite ends, the output of sensor 37 is less sensitive to longitudinal movements of the digit during the measurement period. Thus, a longitudinal movement of the finger, e.g., in the direction of the distal tip, will tend to increase the pressure of the fluid at the distal end of the chamber enclosed within the middle housing part 12, but at the same time will tend to decrease the pressure at the proximal end of that chamber. Since the sensor (37 Fig. 1) senses total volume changes in that chamber of the probe, the two effects will tend to cancel each other, thereby reducing the net effect on the measurement obtained.

The Device of Figs. 4 and 5

Fig. 4 illustrates a probe wherein its housing, generally designated 40, is of a one-piece construction, and its associated internal membrane 41 is also of a one-piece construction. Both the housing 40 and the membrane 41 are of tubular shape, including a closed distal end and an open proximal end. Probe housing 40 illustrated in Fig. 4 is divided into the three segments 40a, 40b and 40c, corresponding to the three housing sections in Figs. 1-3, by two inner annular rings 42, 43, and an outer annular ring 44 at the proximal end of the housing. The distal annular ring 42 carries the Y-bar, shown at 45, for dividing the chamber at

the distal end 40a of the housing into two sub-chambers, as described above with respect to Figs. 1-3.

The two annular rings 42, 43 are inserted into the probe housing 40 at spaced locations therein to define the three chambers within that housing. For this purpose, the inner surface of the probe housing 40 is formed with two annular ribs 46, 47, axially spaced from each other. These ribs are adapted to receive, with a snap-fit, annular recesses 48, 49 formed in the outer surfaces of the two annular rings 42, 43. Ribs 46, 47, are located such that when they receive rings 42, 43, with a snap-fit, the rings press spaced annular portions of the membrane 41 against the inner surface of the housing 40 to define the three separate fluid chambers: namely the distal chamber defined by the distal end 41a of membrane 41 with the distal end 40a of the housing 40; the proximal chamber defined by the proximal end 41b of the membrane 41 with the proximal end 40b of the housing; and the intermediate chamber defined by the middle portion 41c of the membrane with the middle portion 40c of the housing.

The inner surfaces of the annular rings 42, 43 are preferably flush with the inner surface of the housing 40 when the rings are inserted in the above manner. For this purpose, it is preferable to form each of the two annular ribs 46, 47, in an annular recess in the inner surface of the housing 40. This is shown in Fig. 5 with respect to ring 42, wherein it will be seen that such a recess has a depth substantially equal to the thickness of the respective ring (42, 43). The opposite ends of the respective ring (42, 43) are preferably rounded in order to facilitate their insertion into the housing. In addition, a negative pressure may be applied between the membrane 41 and the housing 40 to facilitate the insertion of the rings.

Housing 40 is also formed with the three openings 51, 52, 53, providing communication between the three chambers, the pressure source (35, Fig. 1), and the volume change sensor (37, Fig. 1), in the same manner as described above.

The Device of Figs. 6 and 7

Figs. 6 and 7 illustrate a probe construction wherein the closed distal end, therein designated 61, of the housing, and its end chamber 71, are of substantially shorter length than the other housing sections 62, 63, and their fluid chambers 72, 73. In such a construction as can be seen in particular from Fig. 7, most of the end fluid chamber 71 in the closed distal end section of the housing is forwardly of the distal tip of the patient's finger, and very little of that chamber envelops the finger.

In addition, a tube 74 connects the proximal chamber 72 to a pressure source, and a second tube 75 connects the intermediate chamber 73 to a volume change sensor, as described above with respect to Figs. 1-3. In this case, however, the distal end chamber 71 is fluidly coupled to the proximal open chamber 72 by a further tube 76.

Also, the end fluid chamber 71 in the distal end section 61 of the housing includes an abutment element 77 having a concave surface 77a for receiving the distal tip of the patient's finger when inserted into the probe. The opposite face 77b of the abutment element 77 is fixed to the end wall of the distal end section 61. This end wall could be flat (as shown), or curved, as in the constructions illustrated in Figs. 1-4.

Since the intermediate housing section 63 and the proximal end section 62 enclose substantially the complete length of the patient's finger, with little of it being enveloped by the distal end section 61, the probe is held quite firmly on the finger even without the use of the U-bar (e.g., 24, Figs. 2, 3), as there is little tendency for the fluid in fluid chamber 71 to push out the finger from the probe. This is particularly true if the intermediate chamber 73 is pressurized first.

A further feature in the probe illustrated in Figs. 6 and 7 is the provision of air vents 78 between housing sections 61 and 63, and air vents 79 between housing sections 63 and 62. Such air vents permit any trapped air to be forced out of the probe, allowing the pressurized membranes to occupy the intervening space, and thus to improve coverage of the pressure field over the finger.

The Devices of Figs. 8-10

Fig. 8 illustrates a probe wherein the distal end section, therein designated 81, of the housing is an open cylinder rather than closed (e.g., of thimble shape) as described above; in addition, the open cylinder is closed by the end fluid chamber 91 mounted within and closing the distal end of the cylinder. Thus, an end fluid chamber 91 exposed on its outer side to the atmosphere. Such an arrangement equalizes the pressure applied to the distal tip of the patient's finger.

For this purpose the front-most segment (which is situated mainly in front of the finger tip) is replaced by the open cylinder 81 closed at its outer end by a fluid filled elastic bag defining end chamber 91, which is open to the atmosphere at its front. This exploits the advantages of the Laplace effect (constant pressure over a wide range of volume changes), and removes the need for supplying pressure to a third compartment, as described in the above cited Publication WO 99/63884.

The proximal end section 82 and the intermediate section 83, of the housing, together with their respective fluid chambers 92 and 93, are of the same construction as described above.

Figs. 9 and 10 illustrate a modification in the probe of Fig. 8, wherein the end fluid chamber 91, closing the distal end section 81 of the housing as described above, is provided with a rigid element 96. This element is secured to the open end of the housing section 81 and is enclosed by the membrane defining the end fluid chamber 91. The side of rigid element 96 facing the patient's finger, when received within the probe, is of a concave configuration, as shown at 96a, for receiving the patient's finger. In addition, rigid element 96 is formed with a plurality of through-going holes 96b permitting the free flow of the fluid within the end chamber 91 with respect to both sides of this element.

The probe illustrated in Figs. 9 and 10 further includes air vents 98 between the distal end section 81 and the intermediate section 83 of the housing,

and further vents 99 between the proximal end section 82 and the intermediate section 83 of the housing, as described above with respect to Figs. 6 and 7.

As seen in Fig. 10, most of the end fluid chamber 91 in the closed distal end section 81 is forwardly of the distal tip of the patient's finger, with little of that chamber enveloping the finger, as described above with respect to end fluid chamber 71 in Fig. 7. According to preliminary tests, it appears that the preferred overall length of the housing in the foregoing constructions is about 50 mm, sufficient to cover the first two phalanges of a patient's finger. In a tested construction, the distal section was 12 mm, the middle end section was 23 mm, and the proximal section was 15 mm. As indicated above, best results were found when the middle section, containing the sensor, is longer than each of the two end sections.

Other Variations (Figs. 11-14)

In the above described constructions, preferably the middle section of the probe serves as the sensing site, and the two end sections serve to buffer the sensing site against venous shock waves and retrograde venous back-flow, to prevent venous pooling, and also to extend the pressure field to the extreme tip of the finger, as in some of the constructions described in Publication WO98/04182.

Fig. 11 illustrates a variation in the construction of the probe of Fig. 1, wherein both the distal segment 11 and the middle segment 12 are used as the sensing sites. In all other respects, the probe in Fig. 11 is constructed and operates in the same manner as described above with respect to Fig. 1.

It will also be appreciated that the inner rings, 42, 43, and 44, as described above with respect to Fig. 4, may also be used in the three-part housing constructions described in the other drawing figures; and that the above-described constructions could include more than one middle part.

As also described in WO98/04182, the collective effect of the uniform pressure field in the new designs illustrated herein also partially unloads arterial wall tension to maximize arterial wall motion. The U-bar 24 could be mounted to the housing to span also the middle section, and even also the proximal end section.

Also, the spaces within the housing between the chambers can be vented to the atmosphere, e.g., by providing holes through the connecting rings 14 and 15 in Figs. 1-3, and in the corresponding portions of the housing 40 in Figs. 4 and 5.

It will also be appreciated that the sensor used with the probes described herein could be of any appropriate type, including those based on changes in optical density, the optical Hall effect, ultra sound, etc., e.g., as described in Publication WO98/04182.

Figs. 12 and 13 illustrate two further variations, wherein the proximal end section of the housing includes a sponge cushion, rather than a pressurized chamber. Thus, Fig. 12 illustrates a construction similar to that of Fig. 2 above, except that the proximal end section 112 of the housing includes a sponge cushion 122, and therefore does not include the connection (opening 32, in Fig. 2) to a pressurized source.

Fig. 13 illustrates a two-section construction somewhat similar to the probe described in WO 98/04182, wherein the proximal end section 140b is similarly provided with a sponge cushion 141b, rather than a connection to the pressure source. The sponge cushions 122 of Fig. 12 and 140b of Fig. 13 could be of sponge rubber or the like.

Fig. 14 illustrates a probe construction similar to that of Figs. 6 and 7, except that the probe includes an optical sensor 180, 181, in the middle section 63 and also in the proximal end section 62. Thus, optical sensor 180 is oriented to measure volume changes from the underside of the finger where a high proportion of the blood vessels are so called arteriovenous anastomoses (AVA), while optical sensor 181 is oriented to measure volume changes from the upper side of the middle phalange of the finger for identifying and characterizing blood flow characteristics where a low portion of the blood vessels are AVA. Either or both optical sensors may be used independently or in contact with the volume change measurement.

It will be appreciated that the probes described herein may be used for all applications described in the above-cited WO98/04182, incorporated herein by

reference, including measuring blood pressure, as well as in the applications described in PCT/IL99/00292, also incorporated herein by reference.

Many other variations, modifications and applications of the invention will be apparent.

WHAT IS CLAIMED IS:

1. A device for application to a body part of a patient to detect a change in the physiological condition of the patient comprising: a housing for receiving the body part; pressurizing means for applying a pressure field around the body part when received in said housing; and a sensor for sensing changes in said body part related to changes in blood volume therein; characterized in that:

said housing includes at least three contiguous but separate sections including a distal end section at its distal tip, a proximal end section at its opposite end, and at least one middle section between said end sections;

said pressurizing means applies a pressure field to the portions of the body part received within at least said distal end section and said middle section of the housing;

and said sensor senses changes in the body part received within said middle section of the housing.

2. The device according to Claim 1, wherein said pressurizing means also applies a pressure field to said proximal end section.

3. The device according to Claim 2, wherein said pressurizing means comprises: deformable membrane means within said housing defining end fluid chambers with said end housing sections, and a middle fluid chamber with said middle housing section; and a fluid pressure source for applying a fluid pressure to all of said chambers.

4. The device according to Claim 3, wherein said deformable membrane means is of resilient elastomeric material.

5. The device according to Claim 3, wherein said housing middle section is longer than said housing end sections.

6. The device according to Claim 3, wherein said housing is configured to receive a digit of the patient; said distal end section is closed and encloses a chamber, for receiving the distal end of the patient's digit; and said proximal end section is open and encloses an additional chamber at the opposite end of the housing and connected thereto by said middle section.

7. The device according to Claim 6, wherein said sensor also senses changes in the distal end of the patient's digit received in said closed distal end of the housing.

8. The device according to Claim 6, wherein said housing is constituted of at least three contiguous parts secured together, including:

a thimble-shaped cap at the closed distal end of the housing;
an annular collar at the open proximal end of the housing; and
an intermediate sleeve secured between the thimble-shaped cap and the annular collar.

9. The device according to Claim 8, wherein said parts of the housing are secured together by a first annular ring which secures said thimble-shaped cap to said intermediate sleeve, and a second annular ring which secures said intermediate sleeve to said annular collar.

10. The device according to Claim 9, wherein said first annular ring mounts a U-shaped bar pressing said membrane means against the inner surface of said thimble-shaped cap to divide the chamber therein into two sub-chambers to be located on opposite sides of the distal tip of a patient's digit when inserted into said housing, and to more firmly retain the patient's digit therein.

11. The device according to Claim 9, wherein said membrane means includes at least three separate membranes, comprising:

a distal membrane having an open end secured by said first annular ring to said thimble-shaped cap to define one end chamber in aid cap;
an annular intermediate membrane having open opposite ends secured to said intermediate sleeve by said first and second annular rings to define said middle chamber in the intermediate sleeve;

and a further annular membrane having one end secured to said annular collar by said second annular ring, and the opposite end secured to said annular collar by a third annular ring to define the other end chamber within said annular collar.

12. The device according to Claim 6, wherein said membrane means is constituted of a single membrane of tubular shape closed at one end and open at

the other end; said device further including a plurality of spaced internal annular rings for clamping spaced annular portions of said membrane to the inner surface of said housing to define said fluid chambers in said housing sections.

13. The device according to Claim 12, wherein the inner surface of said tubular housing, and the outer surfaces of said internal rings, are formed with mating rib and recess formations enabling the internal rings to be snap-fitted within said housing, and to press annular portions of the tubular membrane against the inner surface of the housing to define said chambers.

14. The device according to Claim 13, wherein said mating rib and recess formations are constituted of annular ribs formed on the inner surface of said housing, and annular recesses formed on the outer surfaces of said internal annular rings.

15. The device according to Claim 12, wherein said housing is constituted of one part of tubular shape closed at said distal end and open at its proximal end.

16. The device according to Claim 6, wherein said closed distal end of the housing, and the end fluid chamber therein, are of substantially shorter length than the other housing sections and the fluid chambers therein.

17. The device according to Claim 6, wherein said end fluid chamber in the closed distal end section of the housing includes an abutment element engageable with the distal tip of the patient's digit.

18. The device according to Claim 17, wherein said abutment element is located such that, when engaged by the distal tip of the patient's digit, most of said end fluid chamber is located forwardly of the distal tip of the patient's finger.

19. The device according to Claim 6, wherein said end chamber in the closed distal end section of the housing is fluidly coupled to the fluid chamber in the open proximal end section of the housing.

20. The device according to Claim 6, wherein said distal end section of the housing is an open cylinder and is closed by the end fluid chamber therein mounted within and closing one end of the cylinder.

21. The device according to Claim 20, wherein said end fluid chamber closing the open end of the cylinder includes a rigid element mounted within one

end of the cylinder and enclosed by the membrane defining said end fluid chamber.

22. The device according to Claim 21, wherein said rigid element is formed with holes therethrough permitting the free flow of fluid within said end chamber with respect to both sides of the rigid element.

23. The device according to Claim 22, wherein said rigid element is formed with a concave surface for receiving the distal tip of the patient's finger.

24. The device according to Claim 20, wherein said end fluid chamber closing the end of said open cylinder is a fluid filled elastic bag open to the atmosphere at its front to provide relatively constant pressure over a wide range of volume changes in accordance with the Laplace effect.

25. The device according to Claim 1, wherein said pressurizing means applies a static pressure field of sufficient magnitude such that the heartward-most compartment of said pressure field acts as a venous tourniquet to prevent venous pooling, and retrograde venous blood flow or shockwave propagation into the more distal end of the body part.

26. The device according to Claim 1, wherein said proximal end section includes a sponge cushion.

27. The device according to Claim 1, wherein said sensor is in said middle section of the housing, and there is another sensor in said proximal end section of the housing.

28. The device according to Claim 27, wherein said middle section sensor is an optical sensor at the underside of said middle section, and said another sensor is an optical sensor at the upper side of the proximal end section.

29. The device according to Claim 1, wherein said housing sections further include air vents between said sections venting the interior of the housing to the atmosphere.

30. The device according to Claim 1, wherein said housing sections are of a total length to cover two phalanges of a patient's finger.

31. The device according to Claim 1, wherein said housing sections are of a total length of approximately 50 mm.

32. A device for application to a body part of a patient to detect a change in the physiological condition of the patient, comprising:

a housing for receiving the patient's body part, said housing including at least a distal end section at the distal end with respect to the patient's heart, and a proximal end section at the proximal end with respect to the patient's heart;

said distal end section including pressurizing means for applying a pressure field around the body part when received in said housing, and a sensor for sensing changes in said body part related to changes in blood volume therein;

said proximal end section including a sponge cushion.

33. The device according to Claim 32, wherein said housing also includes a middle section between said end sections, said pressurizing means applying a pressure field around the body part when received in said housing.

34. The device according to Claim 32, wherein said housing consists only of said distal end section and said proximal end section.

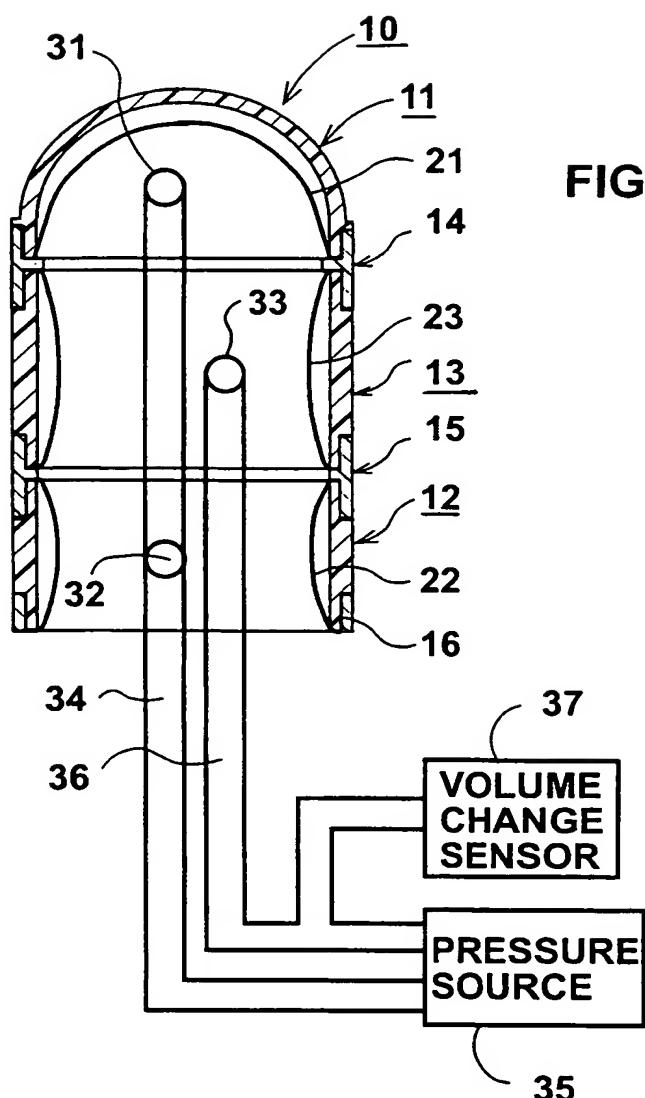
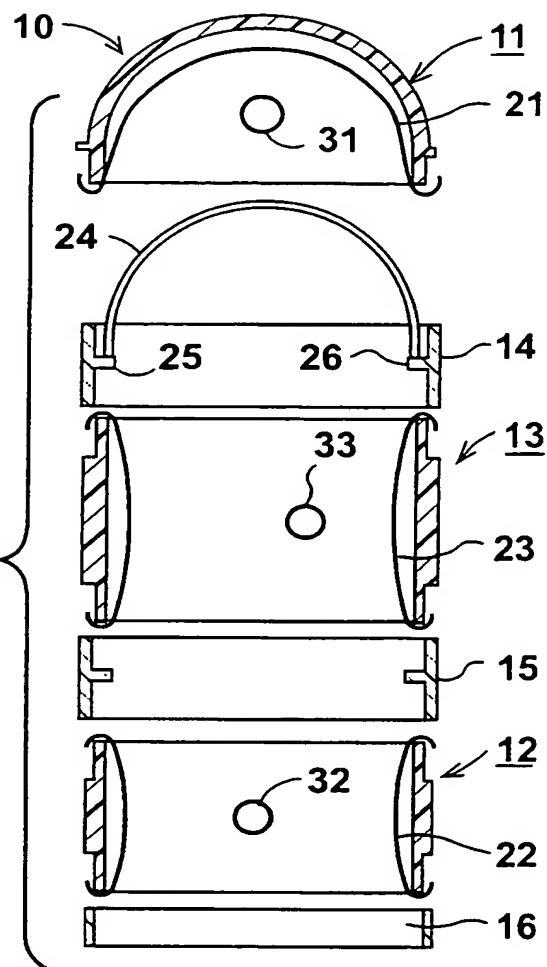
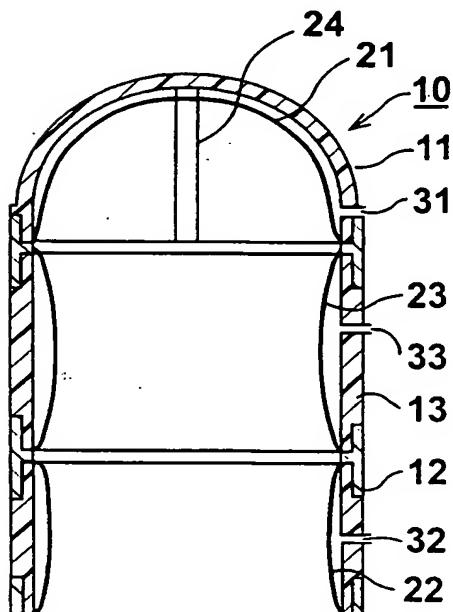
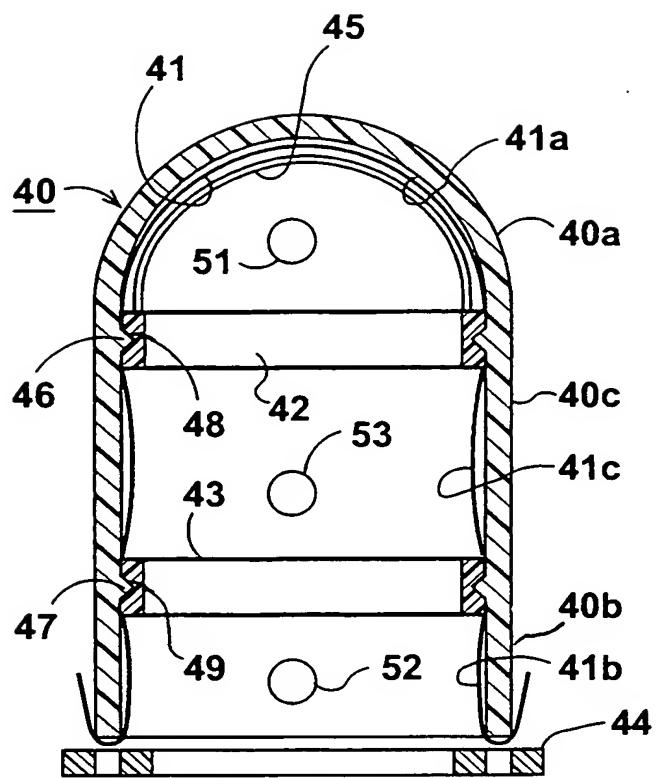
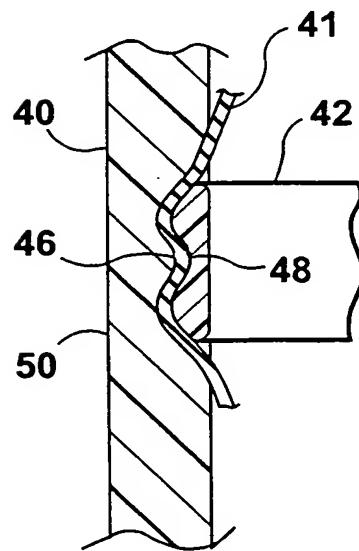
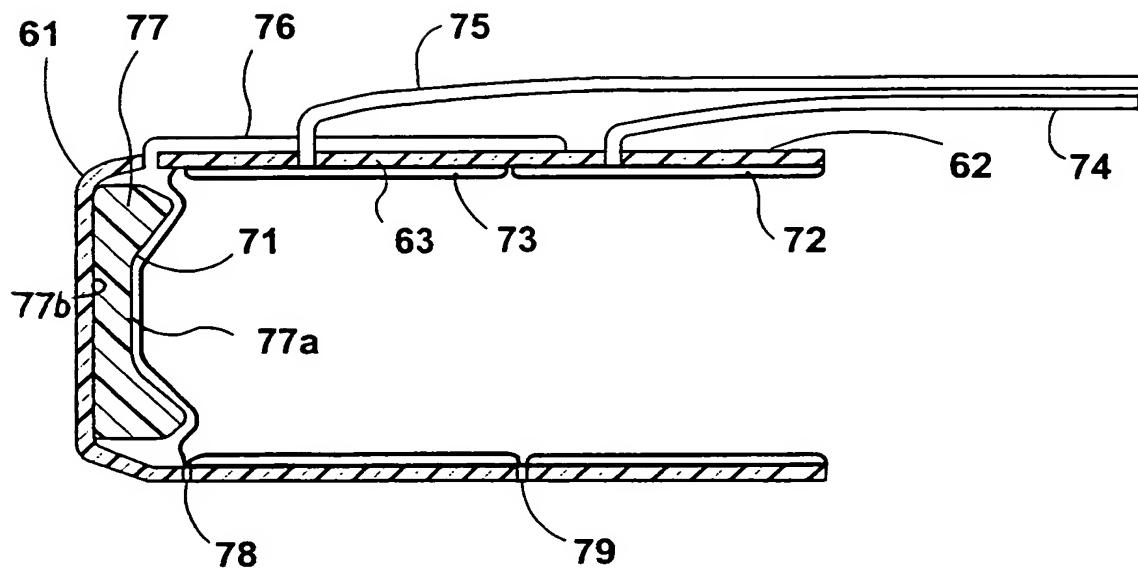
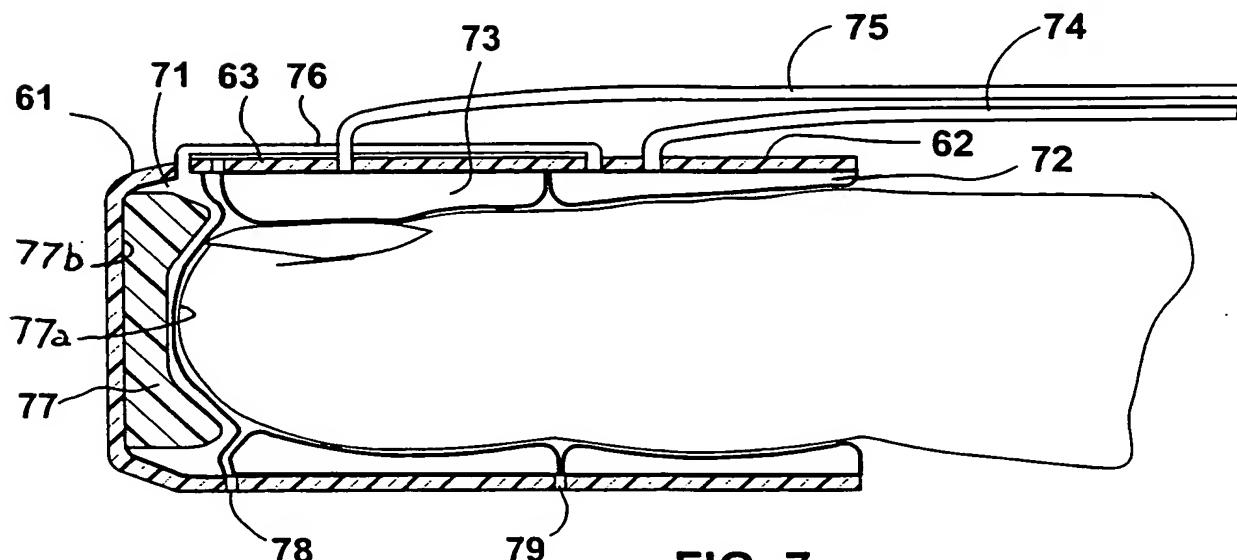
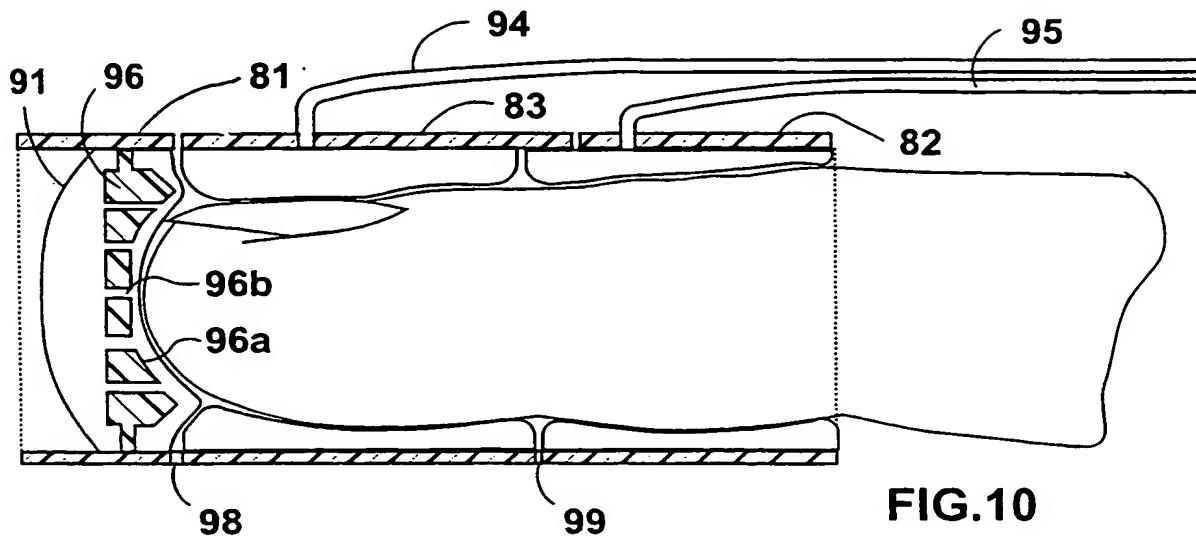
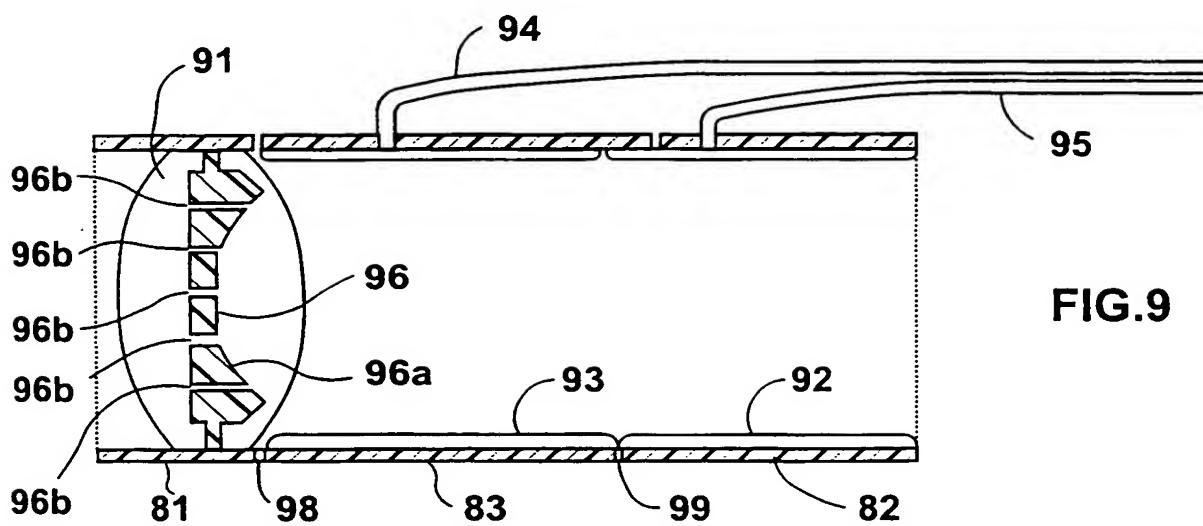
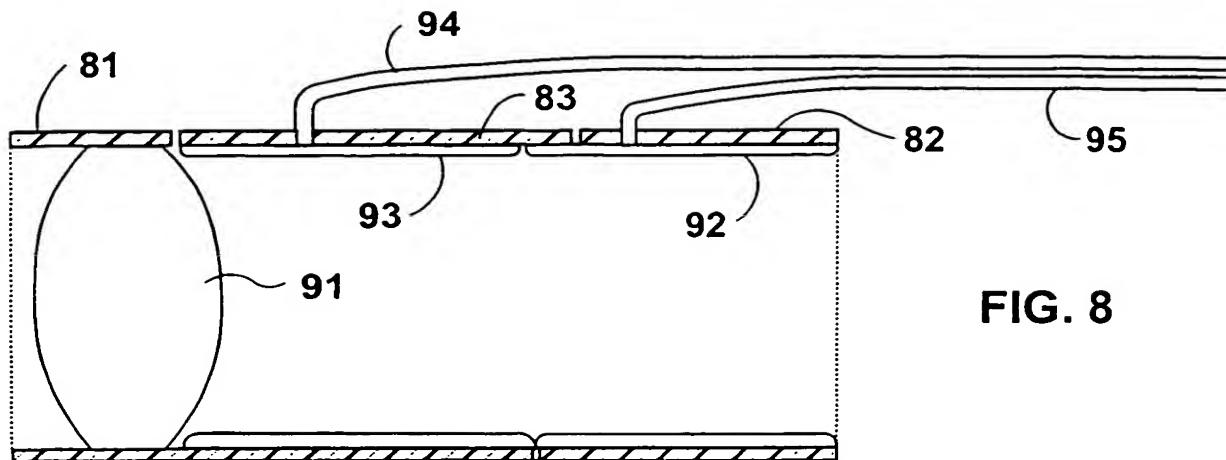
FIG. 1**FIG. 2****FIG. 3**

FIG. 4**FIG. 5**

**FIG. 6****FIG. 7**



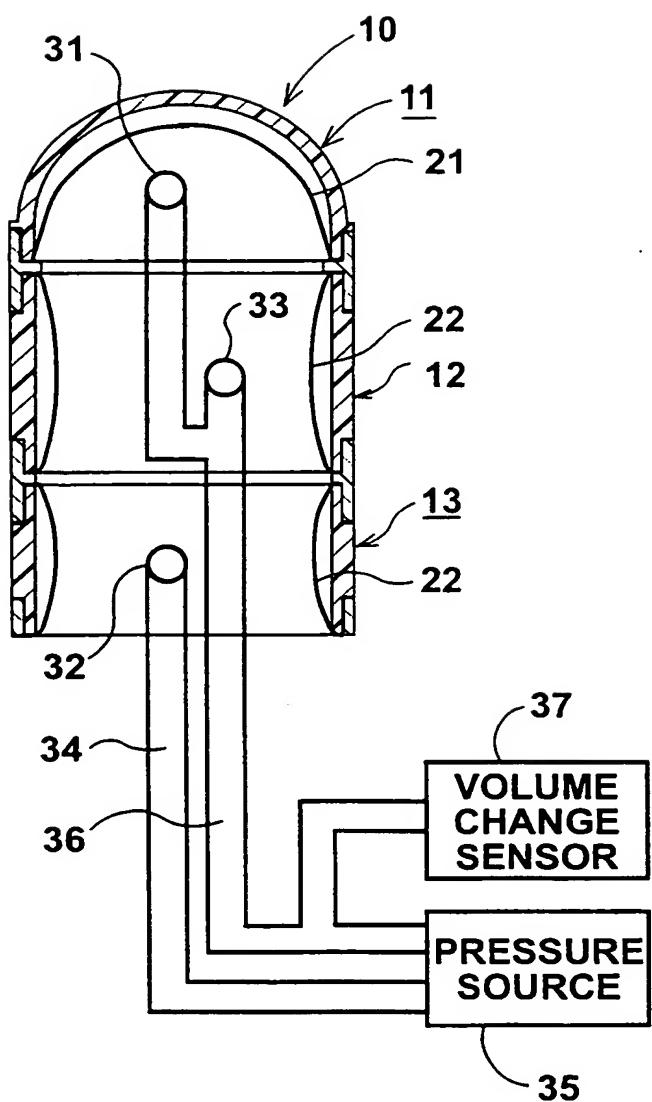


FIG. 11

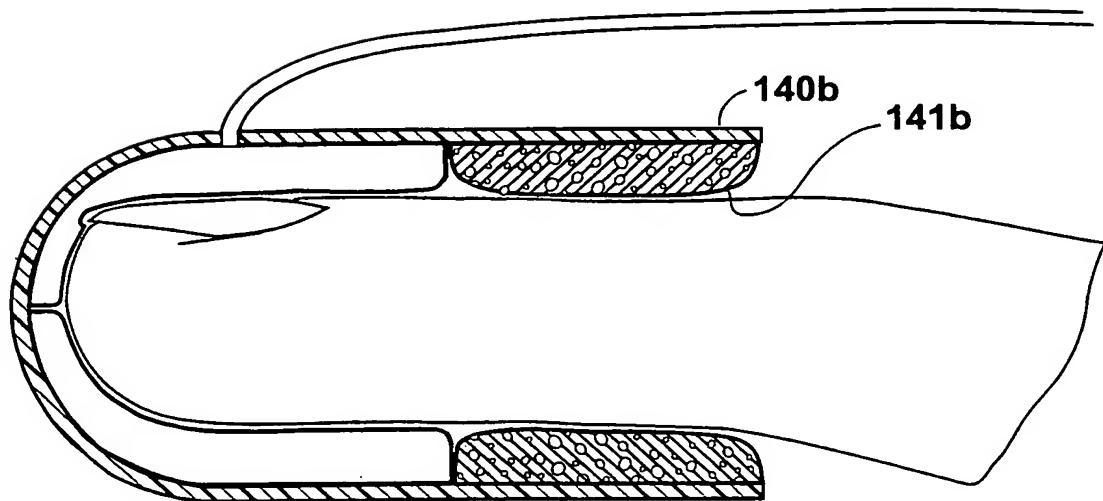
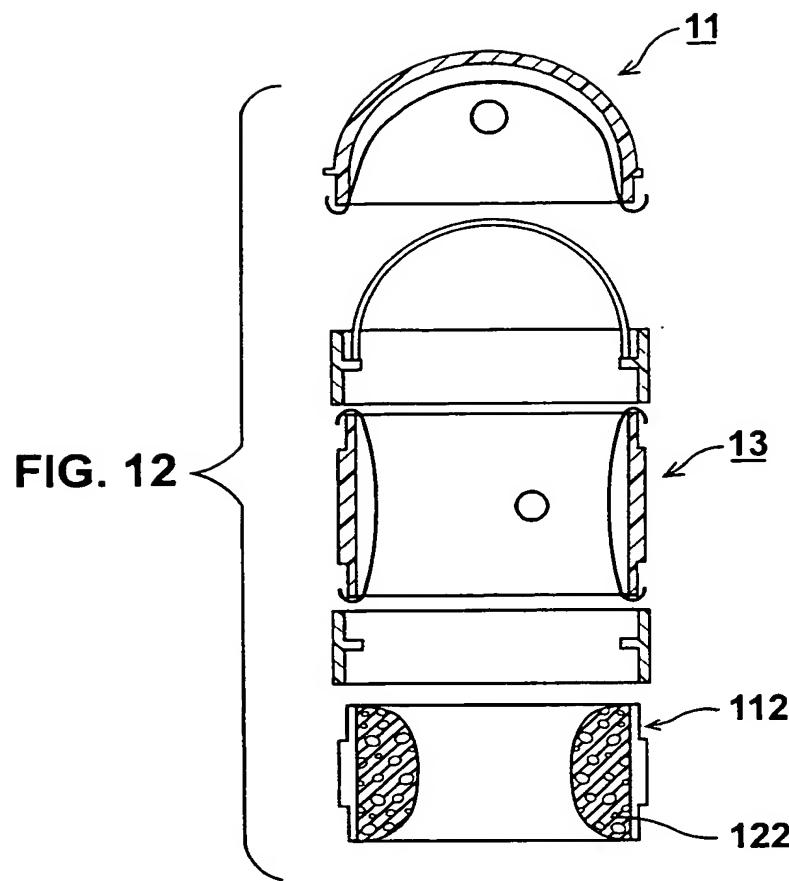


FIG. 13

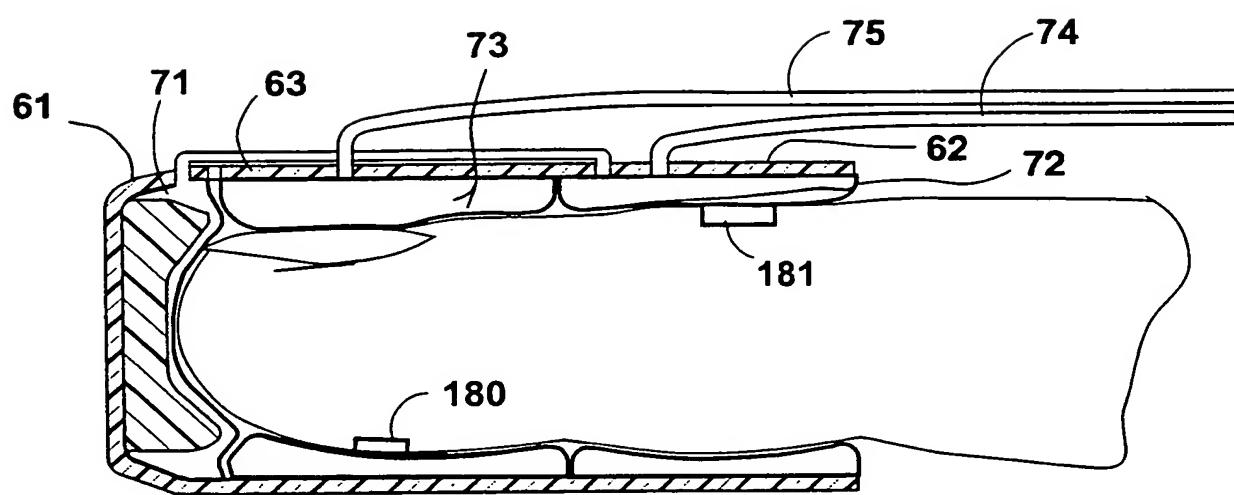


FIG. 14

20083

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
18 January 2001 (18.01.2001)

PCT

(10) International Publication Number
WO 01/03569 A2(51) International Patent Classification⁷:**A61B**(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(21) International Application Number:

PCT/IL00/00403

(22) International Filing Date:

9 July 2000 (09.07.2000)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

130939

14 July 1999 (14.07.1999) IL

(71) Applicant (*for all designated States except US*): ITAMAR MEDICAL (CM) 1997 LTD. [IL/IL]; 2 Haeshel Street, Industrial Park, 38900 Caesarea (IL).

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): SCHNALL, Robert, P. [IL/IL]; 5 Hadafna Street, 27201 Kiryat Bialik (IL).

(74) Agent: EHRLICH, Gal; G.E. Ehrlich (1995) Ltd., 28 Bezalel Street, 52521 Ramat Gan (IL).

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *Without international search report and to be republished upon receipt of that report.**For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.***WO 01/03569 A2**

(54) Title: PROBE DEVICES PARTICULARLY USEFUL FOR NON-INVASIVE DETECTION OF MEDICAL CONDITIONS

(57) Abstract: A probe for application to a body part, such as a finger or toe, of a patient to detect a change in the physiological condition of the patient includes: a housing having at least three contiguous but separate sections, namely: a distal end section at its distal tip, a proximal end section at its opposite end, and at least one middle section between the end sections. A pressure field is applied to the portion of the body part received within at least the distal end section and the middle section of the housing; and a sensor senses changes in the body part received within the middle section of the housing.

THIS PAGE BLANK (USPTO)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 January 2001 (18.01.2001)

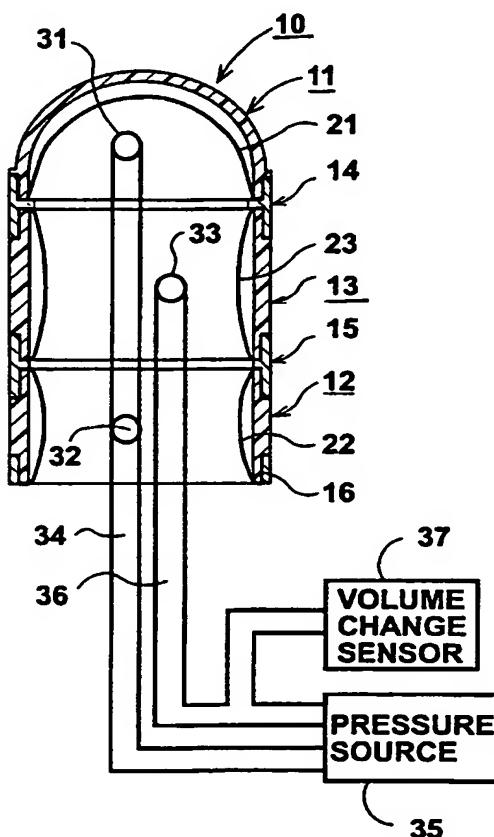
PCT

(10) International Publication Number
WO 01/03569 A3

- (51) International Patent Classification⁷: **A61B 5/00**
- (21) International Application Number: **PCT/IL00/00403**
- (22) International Filing Date: **9 July 2000 (09.07.2000)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
130939 14 July 1999 (14.07.1999) IL
- (71) Applicant (*for all designated States except US*): **ITAMAR MEDICAL (CM) 1997 LTD. [IL/IL]; 2 Haeshel Street, Industrial Park, 38900 Caesarea (IL).**
- (72) Inventor; and
- (75) Inventor/Applicant (*for US only*): **SCHNALL, Robert, P. [IL/IL]; 5 Hadafna Street, 27201 Kiryat Bialik (IL).**
- (74) Agent: **EHRLICH, Gal; G.E. Ehrlich (1995) Ltd., 28 Bezalel Street, 52521 Ramat Gan (IL).**
- (81) Designated States (*national*): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (*regional*): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).**
- Published:
— *With international search report.*

[Continued on next page]

(54) Title: PROBE FOR NONINVASIVE DETECTION OF MEDICAL CONDITIONS



(57) Abstract: A probe (10) for application to a body part, such as a finger or toe, of a patient to detect a change in the physiological condition of the patient includes: a housing having at least three contiguous but separate sections, namely: a distal end section (11) at its distal tip, a proximal end section (12) at its opposite end, and at least one middle section (13) between the end sections. A pressure field is applied to the portion of the body part received within at least the distal end section (11) and the middle section (13) of the housing, and a sensor (37) senses changes in the body part received within the middle section (13) of the housing.

WO 01/03569 A3



(88) Date of publication of the international search report:

25 May 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No. PCT/IL00/00403

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 05/00'

US CL : 600/300;

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/300, 301, 587, 500, 504;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/404182 A2 (GOOR et al.), 05 February 1998, see entire document.	1-34.

Further documents are listed in the continuation of Box C.

See patent family annex.

- Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 DECEMBER 2000

Date of mailing of the international search report

04 JAN 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
ROBERT L. NASSER JR.
Telephone No. (703) 308-3251

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

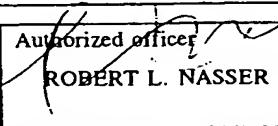
To: GAL EHRLICH GE EHRLICH LTD. 28 BEZALEZ STREET 52 521 RAMAT GAN ISRAEL	RECEIVED 18 JAN 2001 FILE No. <u>20083</u> G.E. EHRLICH (1995)
---	--

**NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION**

(PCT Rule 44.1)

Applicant's or agent's file reference 20083	FOR FURTHER ACTION See paragraphs 1 and 4 below International filing date (day/month/year) <u>04 JAN 2001</u>
International application No. PCT/IL00/00403	Date of Mailing (day/month/year) <u>09 JULY 2000</u>
Applicant ITAMAR MEDICAL LTD.	

1. The applicant is hereby notified that the international search report has been established and is transmitted herewith.
- Filing of amendments and statement under Article 19:**
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
- When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.
- Where?** Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35
- For more detailed instructions, see the notes on the accompanying sheet.
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. **Further action(s):** The applicant is reminded of the following:
- Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.
- Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).
- Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer  ROBERT L. NASSER JR. Telephone No. (703) 308-3251
---	--

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 20083	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IL00/00403	International filing date (day/month/year) 09 JULY 2000	(Earliest) Priority Date (day/month/year) 14 JULY 1999
Applicant ITAMAR MEDICAL LTD.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:
 - contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
- 2. Certain claims were found unsearchable (See Box I).
- 3. Unity of invention is lacking (See Box II).
- 4. With regard to the title,
 - the text is approved as submitted by the applicant.
 - the text has been established by this Authority to read as follows:
The title is too long. See PCT Rule 4.3
New Title: Probe for noninvasive detection of medical conditions
- 5. With regard to the abstract,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
- 6. The figure of the drawings to be published with the abstract is Figure No. 1
 - as suggested by the applicant.
 - because the applicant failed to suggest a figure.
 - because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL00/00403

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A probe (10) for application to a body part, such as a finger or toe, of a patient to detect a change in physiological condition of the patient includes: a housing having at least 3 contiguous but separate sections, namely: a distal end section (11) at its distal tip, a proximal end section (12) at its opposite end, and at least one middle section (13) between the end sections. A pressure field is applied to the portion of the body part received within at least the distal end section (11) and the middle section (13) of the housing, and a sensor (37) senses changes in the body part received within the middle section (13) of the housing.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL00/00403

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 05/00'

US CL : 600/300;

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/300, 301, 587, 500, 504;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/404182 A2 (GOOR et al.), 05 February 1998, see entire document.	1-34.

Further documents are listed in the continuation of Box C.

See patent family annex.

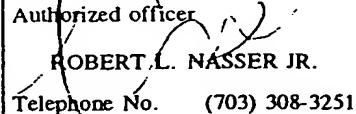
"	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 DECEMBER 2000

Date of mailing of the international search report

04 JAN 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230Authorized officer

ROBERT L. NASSER JR.
Telephone No. (703) 308-3251

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

Date of mailing (day/month/year) 05 April 2001 (05.04.01)	ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/IL00/00403	Applicant's or agent's file reference 20083
International filing date (day/month/year) 09 July 2000 (09.07.00)	Priority date (day/month/year) 14 July 1999 (14.07.99)
Applicant	
SCHNALL, Robert, P.	

- 1. The designated Office is hereby notified of its election made:**

in the demand filed with the International Preliminary Examining Authority on:

16 January 2001 (16.01.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>C. Cupello</p> <p>Telephone No.: (41-22) 338.83.38</p>
---	---

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT**NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS**(PCT Rule 62 and
Administrative Instructions, Section 417)

Date of mailing (day/month/year) 05 April 2001 (05.04.01)	To: Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as International Preliminary Examining Authority
International application No. PCT/IL00/00403	International filing date (day/month/year) 09 July 2000 (09.07.00)
Applicant ITAMAR MEDICAL (CM) 1997 LTD. et al	

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

C. Cupello

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38